

WHAT IS CLAIMED IS:

1. A medical device (110) comprising a unitarily and continuously formed portion (108) having a varying durometer.

2. The medical device (110) according to claim 1, further comprising an inflatable balloon (18 or 118) connected to the unitarily and continuously formed portion (108).

3. The medical device (110) according to claim 2, wherein the inflatable balloon (18) is not unitarily and continuously formed with the unitarily and continuously formed portion (108).

4. The medical device (110) according to claim 1, wherein the unitarily and continuously formed portion (108) comprises a tubular portion (106).

5. The medical device (110) according to claim 4, wherein the unitarily and continuously formed portion (108) further comprises an inflatable balloon (118) unitarily and continuously formed with the tubular portion (106), the inflatable balloon (118) and the tubular portion (106) having different durometers.

6. The medical device (110) according to claim 4, wherein the unitarily and continuously formed portion (108) further comprises an anchor structure (170) unitarily and continuously formed with the tubular portion (106), the anchor structure (170) and the tubular portion (106) having different durometers.

7. The medical device (110) according to claim 6, wherein the anchor structure (170) comprises a malecot (172), a pigtail (174) or a loop (176).

8. The medical device (110) according to claim 4, wherein the tubular portion (106) comprises a catheter shaft (111).

1 9. The medical device (110) according to claim 8, wherein the catheter shaft
2 (111) comprises at least first and second catheter shaft segments (178 and
3 180) of different durometer, the first and second catheter shaft segments (178
4 and 180) being unitarily and continuously formed.

1 10. The medical device (110) according to claim 9, wherein one of the at
2 least first and second catheter shaft segments (178 or 180) comprises a
3 catheter tip (184) and the other of the at least first and second catheter shaft
4 segments (178 or 180) comprises a catheter body (186).

1 11. The medical device (110) according to claim 10, wherein the catheter tip
2 (184) has a greater durometer than the catheter body (186).

1 12. The medical device (110) according to claim 11, wherein the catheter tip
2 (184) includes a distal end (190) and a step or ledge (188) formed in the
3 catheter tip (184) near the distal end (190), and wherein the medical device
4 (110) further comprises a needle (192) receivable in the catheter shaft (111),
5 the needle (192) bearing on it a ring, collar or enlargement (194) engageable
6 with or abutable against the step or ledge (188) in the catheter tip (184).

1 13. The medical device (110) according to claim 10, wherein the catheter
2 body (186) has a greater durometer than the catheter tip (184).

1 14. The medical device (110) according to claim 1, wherein the unitarily and
2 continuously formed portion (108) comprises at least first and second unitarily
3 and continuously formed parts (102 and 104) having different durometers, and
4 a transition zone (105) of continuously varying durometer connecting the first
5 and second parts (102 and 104), the transition zone (105) being unitarily and
6 continuously formed with the first and second parts.

1 15. The medical device (110) according to claim 1, wherein the unitarily and
2 continuously formed portion (108) extends longitudinally, and wherein the
3 durometer of the unitarily and continuously formed portion (108) varies
4 continuously along the length of the portion (108).

1 16. The medical device (110) according to claim 1, comprising a catheter shaft
2 (211) having an outer catheter shaft (114) and an inner catheter shaft (112)
3 received in the outer catheter shaft (114), the outer catheter shaft (114)
4 comprising the unitarily and continuously formed portion (108).

1 17. The medical device (110) according to claim 16, further comprising an
2 inflatable balloon (18) connected to the outer catheter shaft (114) and the
3 inner catheter shaft (112) although not unitarily and continuously formed with
4 either the outer catheter shaft (114) or the inner catheter shaft (112).

1 18. The medical device (110) according to claim 16, wherein the outer
2 catheter shaft (114) further comprises an inflatable balloon (118) unitarily and
3 continuously formed with the unitarily and continuously formed portion (108),
4 the inflatable balloon (118) and the unitarily and continuously formed portion
5 (108) having different durometers.

1 19. The medical device (110) according to claim 1, wherein the unitarily and
2 continuously formed portion (108) comprises an irradiation cross-linkable
3 mixture of a polyamide elastomer and at least one additional cross-linking
4 reactant.

1 20. The medical device (110) according to claim 19, wherein the cross-linking
2 reactant comprises:

3 (a) a difunctional material selected from the class consisting
4 of diallyl adipate; diallyl carbonate; diallyl maleate; diallyl succinate;

diallyl tetrabromophthalate; diethyl diallylmalonate; dimethyl diallylmalonate; and 2,2,6,6-tetrabromobisphenol A diallyl ether;

(b) a trifunctional material selected from the class consisting of 2,5-diallyl-4,5-dimethyl-2-cyclopenten-1-one; diallyl fumarate; diallyl itaconate; 1,3,5-triallyl-2-methoxybenzene; triallyl trimesate (triallyl 1,3,5-benzenetricarboxylate); triallyl trimellitate (triallyl 1,2,4-benzenetricarboxylate); and pentaerythritol triallyl ether;

(c) a tetrafunctional material selected from the class consisting of tetraallyl cis,cis,cis,cis-cyclopentane-1,2,3,4-tetracarboxylate; and N,N,N',N'-tetraallylethylenediamine; or

(d) an aromatic molecule containing at least two ring substituents, each of the ring substituents having labile hydrogens at a benzylic site therein; and

wherein the unitarily and continuously formed portion (108) comprises at least first and second parts (102 and 104) unitarily and continuously formed with one another, at least one of the first and second parts (102 or 104) being exposed to cross-linking irradiation.

21. The medical device (110) according to claim 19, wherein the unitarily and continuously formed portion (108) comprises at least first and second parts (102 and 104) unitarily and continuously formed with one another, and wherein the first and second unitarily and continuously formed parts (102 and 104) of the unitarily and continuously formed portion (108) are exposed to different amounts of cross-linking irradiation.

22. The medical device (110) according to claim 20, wherein the mixture comprises about 1 to about 3 percent by weight of the difunctional material; about 0.5 to about 1.5 percent by weight of the trifunctional material or the aromatic molecule containing at least two ring substituents, each of the ring substituents having labile hydrogens at a benzylic site therein; or about 0.01 to about 1 percent by weight of the tetrafunctional material.

1 23. The medical device (110) according to claim 19, wherein the unitarily and
2 continuously formed portion (108) comprises an amount of the at least one
3 cross-linking reactant sufficient to give the unitarily and continuously formed
4 portion (108) a strength generally about equal to that of a unitarily and
5 continuously formed portion (108) composed of the polyamide elastomer and
6 comparably cross-linked by irradiation, but in the absence of any cross-linking
7 reactant, agent or promoter.

1 24. The medical device (110) according to claim 19, wherein the unitarily and
2 continuously formed portion (108) comprises a mixture of the polyamide
3 elastomer and the at least one cross-linking reactant which has been cross-
4 linked, at least in part, by irradiation with an electron beam or with ultraviolet,
5 X- or gamma rays.

1 25. The medical device (110) according to claim 19, wherein the unitarily and
2 continuously formed portion (108) comprises a mixture of the polyamide
3 elastomer and the at least one cross-linking reactant which has been cross-
4 linked, at least in part, by exposure to about 0.5 to about 60 megarads of
5 radiation.

1 26. The medical device (110) according to claim 19, further comprising an
2 inflatable balloon (18) connected to the unitarily and continuously formed
3 portion (108) although not unitarily and continuously formed with the portion
4 (108).

1 27. The medical device (110) according to claim 19, wherein the unitarily and
2 continuously formed portion (108) comprises a tubular portion (106) and an
3 inflatable balloon (118) unitarily and continuously formed with the tubular
4 portion (106), wherein the inflatable balloon (118) is formed by inflation of the

5 mixture of the polyamide elastomer and the at least one cross-linking reactant
6 after at least part of the mixture has been cross-linked by irradiation.

1 28. The medical device (110) according to claim 20, wherein the mixture
2 comprises an irradiation cross-linkable mixture of a polyamide elastomer and
3 an aromatic molecule containing at least two ring substituents, each of the ring
4 substituents having labile hydrogens at a benzylic site therein, selected from
5 the class consisting of 1,3,5 triethyl benzene; 1,2,4 triethyl benzene; and
6 1,3,5 triisopropyl benzene.

1 29. The medical device (110) according to claim 19, wherein the mixture
2 comprises at least one polyamide elastomer selected from the class consisting
3 of polyester amides, polyether ester amides and polyether amides.

1 30. The medical device (110) according to claim 29, wherein the mixture
2 comprises a nylon block copolymer.

1 31. The medical device (110) according to claim 30, wherein the mixture
2 comprises a nylon block copolymer including polyether blocks separated by
3 polyamide blocks.

1 32. The medical device (110) according to claim 19, wherein the unitarily and
2 continuously formed portion (108) comprises an irradiation cross-linkable
3 mixture of a polyamide elastomer and about 0.5 percent to about 5 percent by
4 weight of at least one additional cross-linking reactant, the cross-linking
5 reactant comprising triallyl cyanurate or triallyl isocyanurate.

1 33. The medical device (110) according to claim 19, wherein the at least one
2 cross-linking reactant comprises diallyl phthalate or meta-phenylene
3 dimaleimide.

34. The medical device (110) according to claim 33, wherein the mixture comprises about 1 to about 2 percent by weight of the at least one cross-linking reactant.

35. The medical device (110) according to claim 19, wherein the mixture comprises: a nylon block copolymer including polyether blocks separated by polyamide blocks, about 3 percent by weight triallyl isocyanurate and about 10 percent by weight nylon.

36. A medical device (110) comprising a unitarily and continuously formed portion (108) having a varying durometer; a catheter shaft (211) having an outer catheter shaft (114) and an inner catheter shaft (112) received in the outer catheter shaft (114), the outer catheter shaft (114) comprising the unitarily and continuously formed portion (108); and an inflatable balloon (18) connected to the outer catheter shaft (114) and the inner catheter shaft (112), although not unitarily and continuously formed with the unitarily and continuously formed portion (108); wherein the inflatable balloon (18) and the unitarily and continuously formed portion (108) have different durometers; and wherein the unitarily and continuously formed portion (108) comprises an irradiation cross-linkable mixture of a nylon block copolymer including polyether blocks separated by polyamide blocks, about 3 percent by weight triallyl isocyanurate and about 10 percent by weight nylon.

37. A medical device (110) comprising a unitarily and continuously formed portion (108) having a varying durometer, and a catheter shaft (211) having an outer catheter shaft (114) and an inner catheter shaft (112) received in the outer catheter shaft (114), the outer catheter shaft (114) comprising the unitarily and continuously formed portion (108); wherein the outer catheter shaft (114) further comprises an inflatable balloon (118) unitarily and continuously formed with the unitarily and continuously formed portion (108), the inflatable balloon (118) and the unitarily and continuously formed portion

(108) having different durometers; and wherein the unitarily and continuously formed portion (108) comprises an irradiation cross-linkable mixture of a nylon block copolymer including polyether blocks separated by polyamide blocks, about 3 percent by weight triallyl isocyanurate and about 10 percent by weight nylon.

38. A medical device (110) comprising a unitarily and continuously formed portion (108) having a varying durometer, the unitarily and continuously formed portion (108) comprising a catheter shaft (111) having at least first and second catheter shaft segments (178 and 180) of different durometer, the first and second catheter shaft segments (178 and 180) being unitarily and continuously formed; wherein one of the at least first and second catheter shaft segments (178 or 180) comprises a catheter tip (184) and the other of the at least first and second catheter shaft segments (178 or 180) comprises a catheter body (186), the catheter tip (184) having a greater durometer than the catheter body (186); and wherein the unitarily and continuously formed portion (108) comprises an irradiation cross-linkable mixture of a nylon block copolymer including polyether blocks separated by polyamide blocks, about 3 percent by weight triallyl isocyanurate and about 10 percent by weight nylon.

39. A process for assembling a medical device (110), the medical device (110) comprising a unitarily and continuously formed portion (108) having a varying durometer, and the process comprising:

creating an irradiation cross-linkable mixture of a polyamide elastomer and at least one additional cross-linking reactant;

forming the mixture into a unitarily and continuously formed portion (108); and

exposing the unitarily and continuously formed portion (108), at least in part, to cross-linking irradiation.

1 40. The process according to claim 39, wherein the step of forming the
2 portion (108) comprises forming the mixture into a tubular portion (106).

1 41. The process according to claim 39, wherein the process is carried out
2 with a mixture comprising: a nylon block copolymer including polyether blocks
3 separated by polyamide blocks, about 0.5 to about 5 percent by weight triallyl
4 isocyanurate and 0 percent to about 25 percent by weight nylon.

1 42. The process according to claim 39, further comprising connecting an
2 inflatable balloon (18) to the unitarily and continuously formed portion (108).

1 43. The process according to claim 40, wherein the step of forming the
2 portion (108) further comprises forming a portion intended for use as an
3 inflatable balloon (118) unitarily and continuously with the tubular portion
4 (106), and wherein the exposing step comprises exposing at least one of the
5 tubular portion (106) and the portion intended for use as an inflatable balloon
6 (118) to cross-linking irradiation.

1 44. The process according to claim 43, further comprising heating and
2 applying pressure to the portion intended for use as an inflatable balloon (118)
3 so as to form an inflatable balloon (118) from that portion.

1 45. The process according to claim 40, wherein the step of forming the
2 portion (108) further comprises forming an anchor structure (170) unitarily and
3 continuously with the tubular portion (106), and wherein the exposing step
4 comprises exposing at least one of the anchor structure (170) and the tubular
5 portion (106) to cross-linking irradiation.

1 46. The process according to claim 45, wherein the step of forming an anchor
2 structure (170) comprises forming a malecot (172), a pigtail (174) or a loop
3 (176).

1 47. The process according to claim 40, wherein the step of forming the
2 portion (108) comprises forming a catheter shaft (111) from the mixture.

1 48. The process according to claim 45, wherein the step of forming a catheter
2 shaft (111) comprises forming at least first and second unitarily and
3 continuously formed catheter shaft segments (178 and 180), and wherein the
4 exposing step comprises exposing at least one of the first and second catheter
5 shaft segments (178 or 180) to cross-linking irradiation.

1 49. The process according to claim 48, wherein the exposing step comprises
2 exposing the first and second unitarily and continuously formed catheter shaft
3 segments (178 and 180) to different amounts of cross-linking irradiation.

1 50. The process according to claim 48, wherein the step of forming a catheter
2 shaft (111) further comprises forming one of the first and second catheter
3 shaft segments (178 or 180) into a catheter tip (184) and the other of the at
4 least first and second catheter segments (178 or 180) into a catheter body
5 (186).

1 51. The process according to claim 50, wherein the exposing step comprises
2 exposing the catheter body (186) to cross-linking irradiation.

1 52. The process according to claim 50, wherein the exposing step comprises
2 exposing the catheter tip (184) to cross-linking irradiation.

1 53. The process according to claim 52, wherein the step of forming a catheter
2 shaft (111) further comprises forming a step or ledge (188) in the catheter tip
3 (184) near a distal end (190) of the catheter tip (184), and wherein the
4 process further comprises introducing a needle (192) into the catheter shaft
5 (111), the needle (192) bearing on it a ring, collar or enlargement (194)

engageable with or abutable against the step or ledge (188) in the catheter tip (184).

54. The process according to claim 39, wherein the step of forming the portion (108) comprises forming the portion (108) into at least first and second unitarily and continuously formed parts (102 and 104), and wherein the exposing step comprises exposing a unitarily and continuously formed transition zone (105) between the first and second parts (102 and 104) to a continuously varying amount of cross-linking irradiation.

55. The process according to claim 54, further comprising placing a shield (196) of varying density between the unitarily and continuously formed portion (108) and a source of cross-linking irradiation, prior to the exposing step.

56. The process according to claim 39, further comprising placing a shield (198) between the unitary and continuously formed portion (108) and a source of cross-linking irradiation, prior to the exposing step.

57. The process according to claim 39, wherein the forming step comprises forming a unitarily and continuously formed portion (108) which extends longitudinally, and wherein said process further comprises placing a shield (196) of varying density between the unitarily and continuously formed portion (108) and a source of cross-linking irradiation.

58. The process according to claim 47, wherein the forming step comprises forming a catheter shaft (111) comprising an outer catheter shaft (114) and an inner catheter shaft (112) received in the outer catheter shaft (114), the outer catheter shaft (114) comprising the irradiation cross-linkable mixture.

59. The process according to claim 58, further comprising connecting an inflatable balloon (18) to the outer catheter shaft (114) and the inner catheter

shaft (112), the inflatable balloon (18) not being unitarily and continuously formed with either the outer catheter shaft (114) or the inner catheter shaft (112).

60. The process according to claim 58, wherein the forming step further comprises unitarily and continuously forming with the outer catheter shaft (114) a portion intended for use as an inflatable balloon (118); and wherein the exposing step is carried out so as to provide different durometers to the outer catheter shaft (114) and the portion intended for use as an inflatable balloon (118), by exposing at least one of the outer catheter shaft (114) and the portion intended for use as an inflatable balloon (118) to cross-linking irradiation.

61. The process according to claim 60, further comprising heating and applying pressure to the portion intended for use as an inflatable balloon (118) so as to form an inflatable balloon (118) from that portion.

62. The process according to claim 39, wherein the forming step is carried out so as to yield a unitarily and continuously formed portion (108) comprising at least first and second parts (102 and 104) unitarily and continuously formed with one another, and the exposing step comprises exposing at least one of the first and second parts (102 or 104) to cross-linking irradiation.

63. The process according to claim 62, wherein the exposing step further comprises exposing the first and second unitarily and continuously formed parts (102 and 104) of the unitarily and continuously formed portion (108) to different amounts of cross-linking irradiation.

64. The process according to claim 39, carried out with a cross-linking reactant comprising:

(a) a difunctional material selected from the class consisting of diallyl adipate; diallyl carbonate; diallyl maleate; diallyl succinate; diallyl tetrabromophthalate; diethyl diallylmalonate; dimethyl diallylmalonate; and 2,2,6,6-tetrabromobisphenol A diallyl ether;

(b) a trifunctional material selected from the class consisting of 2,5-diallyl-4,5-dimethyl-2-cyclopenten-1-one; diallyl fumarate; diallyl itaconate; 1,3,5-triallyl-2-methoxybenzene; triallyl trimesate (triallyl 1,3,5-benzenetricarboxylate); triallyl trimellitate (triallyl 1,2,4-benzenetricarboxylate); and pentaerythritol triallyl ether;

(c) a tetrafunctional material selected from the class consisting of tetraallyl cis,cis,cis,cis-cyclopentane-1,2,3,4-tetracarboxylate; and N,N,N',N'-tetraallylethylenediamine; or

(d) an aromatic molecule containing at least two ring substituents, each of the ring substituents having labile hydrogens at a benzylic site therein.

65. The process according to claim 64, wherein the process is carried out with a mixture comprising about 1 to about 3 percent by weight of the difunctional material; about 0.5 to about 1.5 percent by weight of the trifunctional material or the aromatic molecule containing at least two ring substituents, each of the ring substituents having labile hydrogens at a benzylic site therein; or about 0.01 to about 1 percent by weight of the tetrafunctional material.

66. The process according to claim 39, wherein the process is carried out with an amount of the at least one cross-linking reactant sufficient to give the unitarily and continuously formed portion (108) a strength generally about equal to that of a unitarily and continuously formed portion (108) composed of the nylon block copolymer and comparably cross-linked by irradiation, but in the absence of any cross-linking reactant, agent or promoter.

1 67. The process according to claim 39, wherein the exposing step comprises
2 irradiating the mixture with an electron beam or with ultraviolet, X- or gamma
3 rays.

1 68. The process according to claim 39, wherein the exposing step is carried
2 out at a total fluence of about 0.5 to about 60 megarads.

1 69. The process according to claim 39, wherein the mixing of the polyamide
2 elastomer and the at least one additional reactant is carried out by
3 compounding.

1 70. The process according to claim 40, wherein the tubular portion (106) is
2 formed by extruding the mixture of the polyamide elastomer and the at least
3 one additional reactant.

1 71. The process according to claim 39, wherein the process is carried out
2 with at least one polyamide elastomer selected from the class consisting of
3 polyester amides, polyether ester amides and polyether amides.

1 72. The process according to claim 71, wherein the process is carried out
2 with a polyamide elastomer comprising a nylon block copolymer.

1 73. The process according to claim 72, wherein the process is carried out
2 with a nylon block copolymer including polyether blocks separated by
3 polyamide blocks.

1 74. The process according to claim 64, wherein the process is carried out
2 with an irradiation cross-linkable mixture of a polyamide elastomer and an
3 aromatic molecule containing at least two ring substituents, each of the ring
4 substituents having labile hydrogens at a benzylic site therein, selected from

the class consisting of 1,3,5 triethyl benzene; 1,2,4 triethyl benzene; and 1,3,5 trisopropyl benzene.

75. The process according to claim 34, carried out with a mixture of a polyamide elastomer and about 0.5 percent to about 5 percent by weight of the at least one additional cross-linking reactant, the cross-linking reactant comprising triallyl cyanurate or triallyl isocyanurate.

76. The process according to claim 75, carried out with a mixture further comprising 0 to about 25 percent by weight nylon.

77. The process according to claim 39, carried out with a mixture of a polyamide elastomer and at least one additional cross-linking reactant, the cross-linking reactant comprising diallyl phthalate or meta-phenylene dimaleimide.

78. The process according to claim 77, wherein the process is carried out with a mixture comprising about 1 to about 3 percent by weight of the at least one cross-linking reactant.

79. A process for assembling a medical device (110), the medical device (110) comprising a unitarily and continuously formed portion (108) having a varying durometer, and the process comprising:

creating an irradiation cross-linkable mixture of a polyamide elastomer and at least one additional cross-linking reactant;

forming the mixture into a unitarily and continuously formed portion (108); and

exposing the unitarily and continuously formed portion (108), at least in part, to cross-linking irradiation;

wherein the step of forming the portion (108) comprises forming the mixture into a tubular portion (106);

12 wherein the forming step is carried out so as to yield a unitarily and
13 continuously formed portion (108) comprising at least first and second parts
14 (102 and 104) unitarily and continuously formed with one another, and the
15 exposing step comprises exposing at least one of the first and second parts
16 (102 or 104) to cross-linking irradiation;

17 wherein the exposing step comprises irradiating the mixture with an
18 electron beam at a total fluence of about 0.5 to about 60 megarads;

19 wherein the mixing of the polyamide elastomer and the at least one
20 additional reactant is carried out by compounding, and wherein the tubular
21 portion (106) is formed by extruding the mixture of the polyamide elastomer
22 and the at least one additional reactant; and

23 wherein the process is carried out with a mixture comprising: a
24 nylon block copolymer including polyether blocks separated by polyamide
25 blocks, about 3 percent by weight triallyl isocyanurate and about 10 percent
26 by weight nylon.